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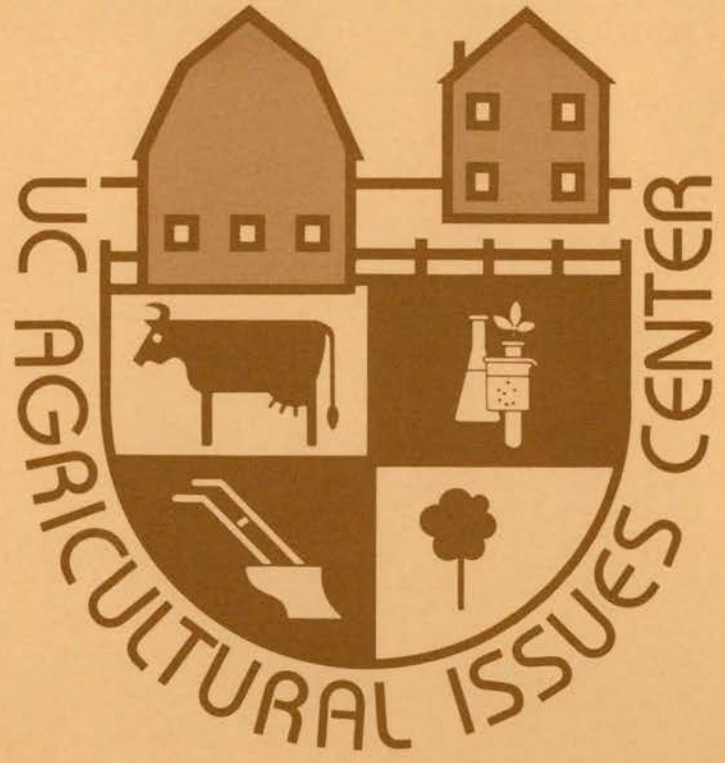
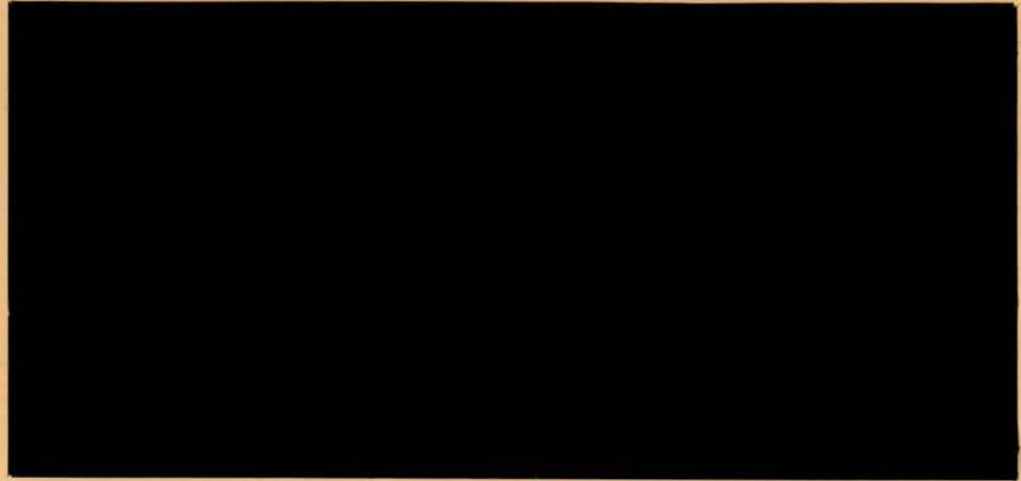
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BIOTECHNOLOGY IN THE FOOD AND AGRICULTURAL
SECTOR: ISSUES AND IMPLICATIONS FOR THE 1990S

by Marvin L. Hayenga

UC AIC Issues Paper No. 88-5, September 1988.

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BIOTECHNOLOGY IN THE FOOD AND AGRICULTURAL SECTOR: ISSUES AND IMPLICATIONS FOR THE 1990S

Marvin L. Hayenga

Products from biotechnology research are beginning to emerge into the commercial market. However, there has been a long gestation period which followed the investor fervor associated with the promise of new products from biotechnology and the spawning of many small biotech research firms to capitalize on these new technologies. Biotechnology in practice is typically considered to include not only genetic engineering, involving recombinant DNA procedures, but some of the older and closely related tools of cell culture, plant regeneration, monoclonal antibodies, embryo transfer, and bioprocess engineering (*Agricultural Biotechnology: Strategies for National Competitiveness*, 1987). These are extensions of age-old techniques of plant and animal breeding and selection that work with the entire organism; the effort is now with individual genes within the organism (Walbot, 1987).

Recently, public research on bovine somatotropin (a growth hormone stimulating increased milk production) has been debated by a variety of groups, including dairy farmers in Wisconsin. There have been demonstrations against field testing of ice-minus bacteria (genetically engineered bacteria to protect strawberry and potato plants from freezing). The European Economic Community has

proposed banning use of growth hormones in agricultural production. The U.S. Congress is raising questions regarding the patenting of genetically engineered animals. These current debates may be leading indicators of the type that may be expected in the future in the public arena as new products from biotechnology begin to emerge at the field-testing level, the regulatory clearance and patent stages, and as they ultimately enter the commercial market.

While the general public seems to be favorably disposed toward genetically engineered products (62 percent consider benefits outweighing risks), 52 percent felt that they are at least somewhat likely to represent a serious threat to people or the environment. (U.S. Congress, 1987).

In 1985, responding to congressional interests, the Office of Technology Assessment (OTA) studied emerging technologies (including biotechnology) using a Delphi approach with 300 scientists to identify the nature of technological change, its timing, and its impact on the structure of agriculture (U.S. Congress, 1986). In addition to the OTA survey study of emerging biotechnologies, there have been two Food and Drug Administration (FDA) surveys on emerging veterinary products from biotechnology and emerging food

biotechnology products and processes (U.S. FDA, 1986; 1988). This paper reports on a 1987-88 University of California survey of 24 biotechnology companies heavily involved in agricultural biotechnology product development. The purpose was to shed light on the types of biotech products on the horizon and the probable timing of their commercial introduction. The findings suggest that the biotech products which have received public attention, and the very few in the commercial market, are only the tip of an iceberg. A number of products will be reaching the marketplace in the next five years, and the volume will greatly expand in the late 1990s. While more exposure and experience with biotechnology may reduce the fear of the unknown, these new products are apt to spawn new issues and concerns, especially regarding their implications, among consumers, farmers, and legislators.

During October 1987 - February 1988, research or product development managers in 24 leading companies involved in agricultural biotechnology research or product development were interviewed in a personal visit or by telephone. Each survey respondent was asked to identify (1) the new biotechnology products likely to enter the marketplace for use in plant or animal agricultural production, or in the food processing industry, in the next decade; (2) the approximate time when the new products will enter the market; and (3) the application in which the products will first be

used. Subsequently, each respondent was asked to identify the most important policy or regulatory issues that may be associated with these new developments. The responses, supplemented by recent biotechnology literature and interviews with academic biotechnologists, provided the basis for the biotechnology forecasts presented here.

Then, drawing from the biotechnology industry survey, a small survey of California farmers, and a variety of other sources, we identify some issues and implications related to these forthcoming developments which may warrant research by social scientists. A comprehensive (*ex ante*) analysis of the probable socioeconomic advantages and disadvantages of these new products—and who gains or loses with their development—could provide critical input to public debate and legislative forums over the next decade. We also briefly consider some implications for land-grant university biotechnology research and Cooperative Extension programs.

Biotechnology Products Now Being Marketed

While the primary biotechnology products which have been controversial and captured national attention (bovine somatotropin, ice-minus bacteria, and most recently, genetically engineered mice), are not yet on the market, there are number of other biotechnology products or processes which are currently marketed or used in the United States. A few

of these have been in use for a number of years; others are recent entries. For example, embryo transplant procedures (transferring multiple embryos from one mother to host mothers) have been employed in animal breeding for a decade or more; the technology continues to be refined and improved. Also, microbial soil inoculants (e.g., *Rhizobium* to enhance nitrogen uptake by plants), silage and hay inoculants (preservatives), and ruminant inoculants or "beneficial bacteria" have been available for a number of years. Fermentation processes involving yeast or other cultures in brewing, baking, and dairy product manufacturing (cheese, yogurt, etc.) have a long history, and improvements in the strains used and process efficiency continue to be made. In particular, increasing microbial densities and yields in fermentation may make some fermentation products commercially feasible which were not previously.

Biopesticides, primarily the *Bacillus thuringiensis* (Bt) natural toxin produced by fermentation processes, have been commercially used as a fairly broad-spectrum alternative to chemical pesticides for several insect species (e.g., flies, mites, moth and butterfly larvae, Colorado beetles). This Bt toxin differs significantly from the original, less pure, Bt used for insect control in the 1960s. This toxin, whether sprayed or genetically incorporated into plants, has no effect on mammals, so there is little human health concern about it. Certain insects, notably bees, are also unaffected.

The first vaccines against animal diseases based on recombinant DNA technology (using coat proteins from viruses in vaccines) have very recently become available for pseudo-rabies in swine. Monoclonal antibodies have also recently entered the market. By fusing a rapidly growing cancer cell with a cell that produces an antibody to a particular substance (it could be a hormone, chemical residue, virus, bacteria, etc.), large quantities of the desired antibody can be produced. These antibodies can be used to recognize a particular disease, a residue, pregnancy, or the presence of heat in a breeding female. For example, recently marketed products include detectors for *E. Coli*, calf scours, feline leukemia, blue-tongue virus, and bovine progesterone (pregnancy test).

Finally, a very recent example of genetic engineering in the food processing industry is an improved glucoamylase enzyme for use in corn wet milling (developed by a subsidiary of CPC, Inc.). By transferring the peptide with enzymatic activity into a more stable organism, the yield of corn syrup and dextrose from the process is significantly improved.

In summary, in 1988 there are a relatively few biotechnology products currently on the market; these include some from genetic engineering in agriculture and food processing.

Biotechnological Innovations on the Horizon

During the next decade, a large number of products from biotechnology will come into use in food production and processing. Some products that will reach the commercial market in the next five years are about to be field tested or subjected to the regulatory clearance process. Most products going commercial in the next five years will come from cell culture and cloning, or from other procedures short of genetic engineering (to avoid the regulatory hurdles and costs imposed on genetic engineered products). But a number of products from genetic engineering are also likely to enter the market, especially transgenic plants and products derived from transgenic bacteria. In addition, some offshoots from human medical research on cancer, AIDS, and the human immunity system may be applied to agricultural problems. We will consider the most probable and important developments forthcoming in animal production, plant production, and food processing, and then examine some issues and implications which may accompany these technological innovations.

Animal Production Biotechnology: The Next Five Years

Growth Promotants

Several major chemical and pharmaceutical companies have had growth promotants for dairy cattle and swine in the field-testing stage of development for

several years. Bovine somatotropin (BST), or dairy growth hormone, has been a subject of controversy among dairymen, legislators, and consumer groups. BST was identified over 50 years ago, but production was not possible on a commercial scale until recently when the growth hormone gene was inserted into bacteria which could reproduce it in large quantities. Original estimates of a 30 to 40 percent increase in milk production per cow are now scaled down to a more realistic figure of 10 to 15 percent. Still there are concerns about dislocation of small dairy farmers. There are also fears about negative consumer reactions to hormones in milk—though there should not be any health issues with this natural hormone. Current industry estimates of the timing of FDA approval and its commercial market introduction, are 1990-91.

Potentially even more important is porcine somatotropin (PST). This new product could lead to some growth rate improvements in market hogs, and to major improvements in carcass fat content (-1/3), lean content (+1/7) and feed required per pound of gain (-1/4) during the last three months of growth. The prospect of significantly improved product quality combined with lower production costs from PST (produced using transgenic bacteria) could begin to be realized by 1990. The impact on the position of pork versus competing meats could be significant, resulting in major structural shifts in the livestock and meat sector. One company already has a plant

capable of producing PST, and another has a plant under construction.

Veterinary Products

As noted in the FDA 1985-86 survey (see Table 1), there is a large number of vaccines based on recombinant DNA in the research pipeline, in addition to a few already on the commercial market. Similarly, monoclonal antibodies developed for disease or drug detection in animals or chemical residue detection in feed will become more prevalent and will be available for on-site tests.

The recent developments in human immunity system boosters and anti-viral prophylactic products could extend to the animal veterinary market in a few years. Anti-virals like alpha interferon or similar anti-bacterials may have possibilities in mastitis or shipping fever control. Immunity system boosters, like interleukin-2 in combination with other products, could find new anti-bacterial uses in the livestock and poultry industries. Microinjection of anti-virals, anti-bacterials, or growth hormones into chick embryos (in the egg) is nearing commercialization in the poultry industry.

Animal Production Biotechnology: In Five to Ten Years

Other biotechnological developments may evolve more slowly. During the late 1990s, growth stimulants for livestock and poultry (produced with recombinant DNA technology) will de-

velop further as increased scientific knowledge of the hormonal checks and balances in commercial animals improves first generation products (especially the somatotropins) and brings on the next generation of growth regulators or stimulators. This second wave includes the growth hormone releasing factor which causes the animal to produce more of its own growth hormone, somatomedins and insulin growth factors (possibly more direct growth stimulants), and somatostatin inhibitors (substances that reduce the effectiveness of the check on growth). In addition to these growth promotants, the luteinizing hormone releasing factor may become available, fostering growth and leanness benefits of male sex hormones (perhaps in beef cattle or swine) without their present disadvantages.

A few experts forecast that the introduction of growth hormone genes into farm animals may become a commercial reality toward the end of the next decade, replacing injection and implantation of growth stimulants. The initial targets of research are the growth, feed efficiency, and improved fat and lean carcass composition effects of the growth hormones, and the discovery of genetic bases for disease resistance. Here are the most likely areas for the first transgenic farm animals—especially in swine where the promise of long-term somatotropin injections is so dramatic. Although genes have already been transferred into pigs, the success rate is low and the cost is

Table 1. Dates of Technical Feasibility and Commercial Availability for Most Frequently Identified Targeted Biotechnology Areas

Area	No. of Citations ^a	Estimated Mean Range for Technical Feasibility	Estimated Mean Range for Commercial Availability
rDNA to Produce Vaccines	186	1987-88	1989-91
Growth Hormones ^b	134	1986-87	1989-91
Monoclonal Antibodies (MABs) to Diagnose Animal Disease or Conditions	106	1986-87	1987-88
Interferons/Interleukens	65	1987-88	1989-91
Other Probes/Vectors ^c	63	1986-87	1988-89
Genetic Modification (Somatic and Germ Line)	60	1988-89	1993-94
MABs to Control Large Scale Disease Problems	56	1988-89	1989-91
Augmentation of Feed Additives	42	1987-88	1989-91
Antibiotics, Drugs	37	1987-88	1989-91

^aIncludes both general citations of the target area, and citations of specific products *within* the target area.

^bIncludes the two most frequently identified products - Bovine Growth Hormone, Porcine Growth Hormone.

^c*Other Probes and Vectors* include a variety of disease technologies, such as rDNA probes to diagnose disease, regulation and enhancement of the immune system, and specialized assays, e.g., Enzyme-Linked Immuno Absorbant Assays.

Source: *Emerging Developments in Veterinary Biotechnology*, U.S. Food and Drug Administration, U.S. Department of Commerce, National Technical Information Service (PI86-222379), July 1986.

extremely high; there are several hurdles to overcome before commercialization of the technology. The recent court ruling that novel transgenic animals can be patented reduces uncertainty about whether innovators in the field will be able to capture a share of the gains from transgenic animal research and development. However, interesting questions are raised about pricing methods and royalty payments for industries new to such procedures.

Plant Production Biotechnology: The Next Five Years

Some new plant biotechnology introductions in the early 1990s will be based on genetic engineering. However, inadequate knowledge about gene mapping for major commercial crops, technical roadblocks to regenerating some genetically engineered plants, and the slow and costly regulatory approval process have meant that biotechnology researchers will rely mostly on tissue

culture or other methods to develop new products for the next few years.

Biological Control Agents

Biological control agents (e.g., bacteria, viruses, fungi) often can be used as alternatives to chemicals in agriculture. As the public concerns about the effects of agricultural chemicals increase and re-registration costs for "old" chemicals lead to their discontinuation, biotech and chemical companies expect that biological controls will be in greater demand. Targeted "pests" may be weeds, insects, nematodes, fungi, viruses, or bacterial infestations (i.e., competing biological systems) which adversely affect the productivity of agricultural crops.

Biological control may also be used against competing organisms not conventionally viewed as pests. The goal is to displace an organism with an adverse characteristic, such as the bacteria which promote ice crystal formation on plants. Microbial decontamination can be used against chemical or organic contaminants of soil (e.g., PCP, PCB). For example, landfills and water supplies contaminated with PCP have been treated with microbial cultures to break down undesirable contaminants on a commercial basis (Crawford, 1987).

The range of biological control agents is potentially quite broad, and is one of the primary focal points of agricultural product development in the biotech industry. Progress is being made in identifying a broader variety of possible

control agents (e.g., more natural toxins for plant pests) and improving their potency, to make them competitive with some chemical alternatives, or at least good second-best substitutes when certain chemicals are no longer available. Because of the higher regulatory hurdles for transgenic plants and other genetic engineering products, than for biological control agents, companies are focusing on the latter. However, there are still significant obstacles to achieving marketable products in biological control. Often only those control agents that are fairly broad in application, or focused on a very important, large volume crop are likely to warrant the investment required to get an agent approved for commercial use.

Federici (1987) has noted some difficulties in developing certain biological control agents. Most microbial insecticides compete favorably with chemical alternatives, especially those based on the *Bacillus thuringensis* (Bt) toxin, are easy to produce at relatively low cost, are "target specific," and are environmentally desirable in that they do not affect other organisms. In contrast, fungal insecticides are inefficient and expensive to produce, and may be practical only for very high value greenhouse crops or strawberries. Also, viral control agents are expensive to produce due to the relatively high cost of meeting regulations stemming from a public perception that viruses might inadvertently spread and become health hazards.

Biopesticides for insect control

appear likely candidates for new product introductions in the next few years. Products using the Bt toxin may be applied to forestry crops, targeting the gypsy moth and the spruce bud worm, and for some large commercial agricultural crops like potatoes (potato beetle) and corn (corn borer). In addition, plant fungal diseases, difficult to control with current technology, are the focus of several new biological control products likely to be introduced as early as 1988. Researchers have been screening soil bacteria to find those with significant anti-fungal activity. These can be reproduced and used in their natural form, though efficiency and environmental survivability may vary, or the genes contributing anti-fungal activity can be identified and used in genetically modifying soil bacteria. Products aimed at fungal diseases in cotton seedlings and several vegetable crops may be available in the next year or two. Several new products for fruit crops and wheat are expected in the early 1990s, and a corn fungal control is likely within the next five years.

These insect and fungal biological controls typically focus on a narrow spectrum of problem organisms. Thus, even as new toxins or controls are identified with potential to broaden the coverage of existing commercial products, the number of new products to be commercially developed seems may be relatively small due to company cost/return criteria which must be met with a limited number of crop applications.

Biopesticides from genetic engineering may become available in the next five years. Their development will probably involve identifying the gene(s) controlling natural toxin production, possibly altering it to make it less sensitive to environmental stresses, and incorporating it into fast growing, more competitive bacteria in the soil root system environment.

Other biological controls use microbial competitors designed to compete with harmful microbes or serve as pathogens for undesirables like weeds. During the next five years, the controversial ice-minus bacteria should become commercially available, possibly as early as 1991. Fruit and berry crops are probable early commercial applications, thereby escaping crop loss associated with freezing temperatures during the critical blossoming period. Strawberries, almonds, cherries, peaches, and pears are the first crops likely to have microbial sprays to provide less susceptibility to frost; grapes, coffee, and other frost-sensitive crops will have similar products by the mid 1990s.

Transgenic Crops

A major class of genetic engineering products that may emerge in the next five years is the transgenic agricultural crop. The first such major biotechnology breakthrough used *E. Coli* bacteria to produce desired plasmids, and introduced them into a modified *Agrobacterium* soil bacteria to transfer agriculturally

useful genes into plants. Many plants are receptive to this method of genetic transmission, including tomato, potato, petunia, tobacco, carrot, poplar, celery, alfalfa, lettuce, flax, rapeseed, sugarbeet, asparagus. However, cereals and other monocots are much less amenable to this method. In particular, the task of regenerating the cells and producing the plants is more difficult. This difference in ease of engineering and reproduction is a primary determinant of which crops will be in the first or second generations of genetic-engineered agricultural crops (Rogers, 1987).

Biotechnologists caution that the successful insertion of an economically important gene into a plant does not imply its immediate availability on the market. Typically, the gene has to be inserted into varieties with other important agronomic characteristics, followed by standard backcrossing and other crop breeding techniques, two to three years of field testing, two years for regulatory clearance, and several years of seed multiplication (some done during the regulatory clearance process) before commercial volumes of the seed are available to market. Thus, four to seven years will frequently elapse from an initial genetic engineering success to market entry.

Several major agricultural chemical or biotechnology companies are field testing plants genetically engineered for herbicide resistance and insect resistance, while more limited work involves viral resistance and fungal resistance. The crop

focus initially has been on the simpler plants whose genetic structures were among the first to be mapped. These are typically viewed as prototypes for more complex, but commercially important crops, yet unmapped. The primary investment in research and field testing of transgenic agricultural crops has been with tobacco, tomatoes, and potatoes; these may be marketed by 1992 or 1993. Meanwhile, crops like corn, wheat, soybeans, and cotton are left on the back burner. However, recent developments in genetic engineering technology, including microinjection for DNA entry through cell walls, and improvements in plant regeneration techniques make grasses, like corn and wheat, good candidates for progress in the mid- to late 1990s.

Genes which give plants resistance to several major classes of herbicides have been identified. Several major chemical companies and biotech companies, or joint ventures between chemical companies and biotech companies, are actively involved in developing herbicide resistant crops. Tomatoes resistant to glyphosphate, sulfonylurea, and bromoxinil are undergoing field tests in 1988, as are rapeseed (canola) and tobacco for some of the same herbicides. (It is interesting to note that the gene for glyphosphate resistance is an enzyme from the petunia.) Alfalfa, corn, and wheat are also candidates for relatively early application of transgenic herbicide resistance. In addition, tissue culture techniques have been used to develop

strains of corn tolerant to a broad spectrum herbicide; these will be on the market in four or five years.¹

While chemicals are available to control most weeds, selecting for the presence of a herbicide-tolerant gene, or transferring such a gene from another species can allow a commercial crop to be immune to herbicide damage while all susceptible weeds nearby, including difficult to control grasses, perish. Ideally, if a crop could be made immune to a particular herbicide with broad-spectrum weed control, requiring a low application rate, and with little or no persistence or toxicological problems, then other more problematic chemical herbicides now in use could be displaced, and fewer trips might be necessary over the field. However, the particular herbicide would still be used. The potential net environmental and economic tradeoffs from these developments are not clear, and warrant further analysis. Total herbicide use could be more or less, as could be the perceived environmental or health effects. In addition, the linkage of individual herbicides with particular varieties of plants and seeds and with their suppliers could have some interesting implications for farm purchasing decisions and farm input market structure and competition.

Insect resistance involving Bt gene transfers has been field-tested in tobacco and tomatoes already, so the market entry could be within four to six years. Prod-

ucts for other crops such as rapeseed, cotton, and potatoes will follow. Natural toxins will also be exploited against other plant predators. These toxins typically have quite specific target insects, so the use of chemicals or biopesticides may still be necessary to control other insects not affected by that toxin. Thus, there could be displacement of some, but not all, chemical insecticides until broader spectrum coverage is achieved by multi-toxin gene transfers into commercial crop varieties.

Virus resistant plants have also been field tested in tomatoes. While viruses have not been considered a major problem in many commercial crops, significant yield increases for certain of these crops were observed in Monsanto's 1987 field test of virus resistance (Rogers, 1987). Tomatoes and potatoes, where virus problems are important, are potential early market transgenic crops with virus resistance.

Value-added Plant Characteristics

There are a number of value-added plant characteristic developments that deserve mention. Several biotech companies have been developing "higher solids" tomatoes, potatoes, and onions to reduce the tonnage processed per unit of output, and related energy and waste treatment expense. These usually are based on standard genetic selection procedures, though genetic engineering is also being

1. For an excellent discussion of genetically engineered crop resistance, see Giaquinta (1986).

explored to achieve the same goals.

At least one company has test-marketed new strains of carrots, celery, and other vegetables which have more crispness, sweetness, or less stringiness, etc. In the research pipeline, there are a number of products like fluffier popcorn, perhaps with its own salt and butter flavors, seedless peppers, pineapple with novel colors or flavors, and naturally low caffeine coffees developed using tissue culture methods. Bruise tolerance and ripening or softening characteristics are areas where progress is being made in some products, where initial market entries within five years are a possibility. A few companies are nearing commercial development of alfalfa with increased leaf storage protein (for livestock feed). Others are working on oilseeds (like rapeseed or sunflower) with a higher processing yield of oil or more desirable fatty acid composition (e.g., high oleic acid) for either nutritional properties (degree of saturation) or enhanced shelf-life (of the oil itself or the food products using it).

When tissue culture methods are used, the successful development of a value-added plant characteristic still takes several steps before the new strains have much market impact (usually four to seven years), even without the more extensive field-testing and regulatory clearance procedures required for genetically engineered products. While only a relatively few value-added products will enter the market during the next few years, several others will quickly follow.

The initial entry in each class of product innovation paves the way for others.

Genetic engineering is being used to introduce color genes from one flower to others. For example, genes conferring blue colors to petunias can be transferred to roses, carnations, or chrysanthemums to provide some unique ornamentals in the next few years. And genetic introduction of a human growth hormone into tobacco could result in an agricultural plant being used as a factory to produce pharmaceutical products.

Other Near-Term Plant Production Innovations

Micropropagation of cloned plant embryos is another new technique that will probably be developed in the near future. By using tissue culture to differentiate and clone improved plants, then encapsulating the embryos and using them instead of seed, genetic purity can be assured, disease exposure can be limited, and the time involved to produce an adequate supply of seed, sharply reduced. Companies are now applying these techniques to such diverse crops as potatoes, cashews, and date palm.

Plant Production Biotechnology: In Five to Ten Years

Commercial product introductions from biotechnology are likely to increase in number and importance five to ten years from now. Initial developments now and in the near future are expected to pave the way in the regulatory arena,

and gradually lead to quicker approvals as more knowledge and experience are gained with genetically engineered organisms. Product development can be based on more complex technology and in more scientifically difficult, but commercially important plant, animal or food processing applications. Initial consumer fears of biotech-related products may dissipate as people experience innovations without any negative consequences, reducing the cost associated with new product introductions.

Some of the new product possibilities on the horizon may emerge later than expected. Often, the first products of biotechnology are developed for a species that is simple to work with or where the knowledge base is most advanced (e.g., tobacco and tomatoes that are gene mapped). These serve as a prototype for subsequent applications; later, the techniques will be applied to a broader array of plants and animals. Most biotech companies suggest that the commercial market sales potential typically has to exceed \$10 million annually, or that product does not warrant the research and development investment required. Many products that could reach the market in ten years are in the initial laboratory testing and refinement stage now; perhaps their development potential has not been fully evaluated yet. And over time the chances of problems cropping up that preclude market entry increase. Thus, the crystal ball of the biotech company managers and university scientists

gets cloudy. Despite that, the interviews with biotechnology experts reported here, provided a picture of some likely patterns of biotechnology innovation during the last half of the next decade.

Generally, there will be only a very limited number of market introductions based on genetic engineering in the next five years. Some transgenic crops are just beginning to emerge, along with a number of engineered microbial products or processes that are starting to play a role in crop production. These developments are likely to expand considerably by the late 1990s.

Transgenic plant product applications will probably be much more frequent in the last five years of the next decade. While plants now undergoing field testing involve *single* gene transfers for herbicide tolerance, insect resistance, and viral resistance, or *single* gene deletion for the ice-minus bacteria, later both plant and microbial products will probably involve combinations of genes (or toxins) for a much broader array of effects. Multiple gene transfers will be needed to achieve desired changes in leaf design, for more effective photosynthetic activity, moisture retention capability, or tolerance of moisture and temperature stress; improved standability; and increased yield in major agronomic crops. These more complicated targets for biotech research may begin to be realized in the late 1990s in some large volume grain and oilseed crops.

Value-added food products using

cell culture or genetic engineering could become much more prevalent in processing and in the consumer market in the late 1990s. Industrial or pharmaceutical products could be produced using agricultural crops or farm animals as the factory (e.g., drugs produced by tobacco or dairy cows). The fragrances, flavors, and colors produced with transgenic plants should be noteworthy. But, bigger steps will be involved in manipulating oil yields and the fatty acid composition of soybeans, the protein levels and amino acid composition of major grains, and the starch composition of products like corn and rice. Consider, for example, the suggestion of one expert: A gene for the omega-3 fatty acid from fish (considered desirable for persons with high cholesterol) may be incorporated into a major oilseed like the soybean, sunflower, or rapeseed. The nutritional, taste, textural, and shelf-life characteristics of major food products could be affected in significant ways in the late 1990s, though the regulatory and biological time lags in transgenic plants probably will delay their major impacts until the 21st century.

Biotechnology Advances in Food Processing: The Next Decade

During the next five years, a relatively small number of products will be emerging from the biotech research pipeline which will change the characteristics of the ultimate consumer food product, or the product being further processed. Most of these will be products of tissue

culture or related techniques, rather than genetic engineering. In some cases, natural components of foods can be isolated and cloned into a producing organism, possibly a plant or, more likely, a bacteria or yeast. Then, fermentation processes can be used to produce large quantities of these natural components. In other cases, plant cells with desired characteristics can be cultured to rapidly reproduce more biochemically complex flavors or other characteristics which reflect more fully the essence of the natural product. In addition to food ingredients or new food products with improved consumer or processing characteristics, new industrial or pharmaceutical products may be forthcoming from the plant or microbial production process. The somatotropins for pork production are an excellent example of a fermentation product to be sold by animal health product companies, causing consumer pork products to be lower in fat content.

Most biotechnology industry members surveyed considered the improvement of consumer or processing characteristics of food products to be a slow process, with major breakthroughs unlikely in the next five years. There are a number of areas in food processing technology where small improvements are more imminent. However, food industry participants were reluctant to provide details when proprietary products were under development. Drawing from our industry survey, the 1988 FDA survey, and an excellent status report on food

biotechnology by an Institute of Food Technology expert panel (*Food Technology*, 1988), it appears that the most significant areas of progress in food processing are likely to be in enzyme technology and in fermentation products and processes. Some of these food advances coming from biotechnology may go unnoticed or be of little concern to the general public, since they will be developed at the processing level without obvious direct impact on consumers.

Enzymes are important in the production of high-fructose corn syrups, brewing, baking, dairy processing, and meat tenderization. Recently Pfizer has developed a genetically engineered enzyme (rennet) which can be produced by fermentation rather than by extraction from byproducts of beef packing, significantly improving its availability for cheese makers. Enzyme immobilization by attaching an enzyme to a stable supporting material is likely to significantly enhance enzyme viability in more efficient continuous production processes. Enzymes such as lipases for fats or proteases for proteins can be made to function in processing environments that previously were inhospitable; now these more complex fat or protein molecules can be broken into components with different characteristics (enhance or eliminate certain flavors). A new alcohol oxidase enzyme may facilitate oxygen absorption in food packages, increasing shelf life. Also enzymes are being developed to facilitate measurement of such

product attributes as alcohol content, and facilitate quality control in food production and processing. Genetic engineering now offers the opportunity for more than one enzyme to be combined with other materials to reduce processing steps and time (e.g., a genetically engineered yeast strain with an enzyme added to simultaneously produce alcohol and reduce the carbohydrates in light beer production, thus speeding up the brewing process).

The fermentation process is the other area where some significant biotechnology innovations may emerge in the next five years. Some examples derived from an expert panel of food technologists are listed in Table 2. Molds, yeast, or bacterial fermentation processes now provide many of our food ingredients (e.g., vitamins, amino acids, enzymes, antioxidants), in addition to the consumer products that we more typically associate with fermentation—beer, sourdough bread, cheese and yogurt, etc.

With increased microbial densities and yields from fermentation processes that are now feasible, many more products from fermentation will be able to be produced commercially, not just pharmaceutical products, cosmetics and colors that sell at extremely high value per pound. The Japanese production of royal purple pigments via fermentation is one example.

One of the primary near-term applications of biotechnologies is in improving starter culture (bacteria) efficiency; the light beer technology

Table 2. Some Possibilities for Microbial Production of Actual and Potential Food Ingredients

<u>Ingredient</u>	<u>Function</u>	<u>Producing Organisms</u>
Acetic acid	Acidulant	<i>Acetobacter pasteurianus</i>
N-acetyl tripeptide	Immune enhancer	<i>Bacillus cereus</i>
D-arabitol	Sugar	<i>Candida diddensii</i>
Beta-carotene	Pigment	<i>Blakeslea trispora</i>
Chrysogenin	Pigment	<i>Penicillium chrysogenum</i>
Citric acid	Acidulant	<i>Aspergillus niger</i>
Citronellol	Fruity flavor	<i>Ceratocystis spp.</i>
Curulan	Thickener	<i>Alcaligenes faecalis</i>
Diacetyl	Buttery flavor	<i>Leuconostoc cremoris,</i> <i>Streptococcus lactis</i>
Dextrans	Thickeners	<i>Leuconostoc mesenteroides</i>
Emulsifier	Emulsification	<i>Candida lipolytica</i>
Fatty acid esters	Fruity fragrances	<i>Pseudomonas spp.</i>
Gamma-decalactone	Peach fragrance	<i>Sporobolimyces odorus</i>
Geraniol	Roselike fragrance	<i>Kluyveromyces lactis</i>
Glycerol	Humectant	<i>Bacillus licheniformis</i>
Glutamic acid	Flavor enhancer	<i>Corynebacterium glutamicum</i>
Lactic acid	Acidulant	<i>Streptococci and lactobacilli</i>
Leucine	Amino acid	<i>Brevibacterium lactofermentum</i>
Lysine	Amino acid	<i>Corynebacterium glutamicum</i>
Mannitol	Sugar	<i>Torulopsis mannitofaciens</i>
Methanol	Flavor	<i>Pseudomonas putida</i>
3-methoxy-3-isopropyl-pyrazine	Potato odor	<i>Pseudomonas perolens</i>
Methylbutanol	Malt flavor	<i>Streptococcus lactis var maltigenes</i>
3-methylbutylacetate	Banana fragrance	<i>Ceratocystis moniliformis</i>
Monascin	Pigment	<i>Monascus purpureus</i>
Nisin	Antimicrobial	<i>Streptococcus lactis</i>
5-nucleotides	Flavor enhancers	<i>Corynebacterium glutamicum</i>
6-pentyl-2-pyrone	Coconut fragrance	<i>Trichoderma viride</i>
L-phenylalanine	Aspartame precursor	<i>Bacillus polymyxa</i>
Proline	Amino acid	<i>Serratia marcescens</i>
Sesquiterpenes	Fruity fragrance	<i>Lentinus lepideus</i>
Surfactant	Wettability	<i>Bacillus licheniformis</i>
Tetramethylpyrazine	Nutty flavor	<i>Bacillus subtilis,</i> <i>Corynebacterium glutamicum</i>
Thermogelable polysaccharides	Thickeners	<i>Argobacterium radiobacter</i>
Vitamin B-12	Vitamin	<i>Propionibacterium</i>
Xanthan gum	Thickener	<i>Xanthomonas campestris</i>
Xylitol	Sweetner	<i>Torulopsis candida</i>

Source: *Food Technology*, January 1988.

mentioned above is one example, while cheese cultures are another prime area of new product development. Several strains of microbes in or near the regulatory clearance stage enhance flavor development in cheese production (a novel lipase enzyme has recently been introduced commercially), speed up the ripening process, or serve as inhibitors to viruses or other pathogens which can develop in the production process. Genetically engineering pathogenic resistance into the culture organisms could inhibit such problems as listeria or salmonella infections prone to develop in cultured consumer products.

Other fermentation processes (meat, vegetables, dairy) are being developed: more stable lactose utilization; purer starter cultures in meat fermentation to reduce staphylococcus infection outbreaks; and novel procedures to improve nutritive quality, product texture, or produce new flavor enhancers, sweeteners, natural flavors, or acidulants. For example, the peptide thaumatin which has extreme sweetness has been isolated from West African fruit. If some after-taste problems can be solved, genetic engineering of that peptide into bacteria and fermentation production processes could result in another low caloric natural sweetener.

Two other areas of food processing advances also deserve mention. Cell culture techniques are being used to produce natural vanilla, grape, and strawberry flavors from cells of those plants,

with other fruit or berry flavors as possibilities in the next few years. Product yields are often many times greater than found in the native plant, making this a potentially commercial source of high value natural products providing desirable flavors, colors, preservatives, or nutritional supplements (*Food Technology*, 1988).

Textural changes in food products utilizing bioengineering techniques provide the basis for some potential new products in the next few years. Hydrolyzing proteins or mechanical means of protein structure modification can bring about textural changes which can greatly change perceived food characteristics. For example, the recently announced Simplese low-calorie fat substitute (restructured milk and egg protein) could potentially reach the dairy products market in the next few years.

Collectively, the biotechnological advances in the food and agricultural sector in the next decade seem likely to speed up the rate of technological change, leading to changes in efficiency, productivity, input use, production risk, and product quality, and to new consumer or industrial products from agriculture. The products emerging from the biotech research and development pipeline show promise for bringing many beneficial changes, but they also raise many questions and concerns. In the next section, a number of these issues raised by farmers, consumers, academics, biotech companies, and government policy makers are

outlined to help social scientists and others interested in biotechnology and its implications begin planning a research agenda and provide useful input to the biotechnology policy dialogue expected during the next five to ten years.

Philosophical, Environmental, Ecological Issues

There are philosophical, environmental, and ecological issues associated with biotechnology to which social scientists might contribute some expertise. These very issues may have a significant impact on consumer and producer acceptance of biotech products, on regulatory and food labeling hurdles and costs, on perceived business risks of new product research and development, and on priorities in allocating public sector research funds. Some of these behavioral factors and their socioeconomic implications need analysis.

Many biotech industry members, as well as some scientists in the university community, have been surprised at the issues raised and the strength of the concern or opposition to innovations from biotechnology. Industry members, drawing from their own experience and the experience of others dealing with the public concerning biotechnology, frequently mention the public's concern about the unexpected and undesirable effects possible from genetically engineered species. One can speculate that this may reflect the lay public's fear of the unknown, its perception that adverse

effects of new developments will be discovered many years hence, or, possibly, the concept that bacteria or viruses released in the environment equate with disease. An OTA survey found 52 percent of the public believing that genetically engineered products are at least somewhat likely to represent a serious danger to people or the environment (OTA, May 1987).

A few industry survey respondents raised the philosophical issue about whether it is right to manipulate or regulate the genetic makeup of any living organism, be it plant or animal—but especially human. While the general public expressed little concern about this issue in the OTA survey, religious leaders often do. They are more worried about human genetic manipulation than with plant or animal gene manipulation or with mixing genes among species (Miller, 1985).

One or two agronomists among the biotechnologists in our survey questioned whether genetic engineering of plants might pollute the long-term evolution of natural genetic change. Will the genetic base become narrower and more prone to the problems (like corn blight in the early 1970s) or broader as genes from various species are introduced into the gene pool of certain crops? Will the potentially greater selection pressures brought on by genetically engineered plants tolerant to specific chemicals or pests, or by Bt toxins in plants or biopesticides, lead to resistant varieties of weeds or other pests? Resis-

tance to antibiotics is sometimes pointed to as an example of what could occur in certain applications of biotechnology.

The issue raised most frequently by industry biotechnologists springs from their own concern about the regulation of biotechnology. In particular, they questioned whether products of recombinant DNA technology should be regulated more stringently than products emerging from tissue culture or other less sophisticated techniques. While some agencies appear to treat them the same (e.g., the FDA), others have more stringent regulatory requirements for containment of genetically engineered organisms in the lab and for field-testing of genetically engineered plants or microbes. Yet, the specific nature of genetic changes is said to be much more difficult to control in products derived from standard genetic selection, or from induced or natural mutations. Biotechnologists indicate that there often is much less chance of unexpected results from transferring material with known genetic characteristics from one organism to another than there is with chemically induced mutations. Thus, regulations could be more tailored, based on the specific knowledge base and risk of each genetically engineered organism.

Consumers concerned with chemical residues in food and environmental activists concerned with chemicals in the environment raise a different question: Can biotechnology displace harmful chemicals in our food and environment?

One might expect an affirmative answer when considering biotechnology products able to degrade oil spills or soil contamination, and biopesticides intended to serve as substitutes for chemical pesticides. However, the development of herbicide resistant crops prompts the lay public and many scientists to expect more use of chemicals for these crops, not less. In response, biotech and chemical companies developing crops with herbicide resistance suggest that other herbicides will be displaced, and the net use of chemical herbicides probably will be less. Further in-depth analysis of a variety of crops engineered for herbicide resistance, insect resistance, and/or fungal resistance is necessary to determine the net impact of each genetic manipulation and the aggregate impact of all such changes on the environment.

Socioeconomic Issues

Regulatory

The major socioeconomic issues raised by biotech industry members are integrally related to the public concerns about possible unexpected effects of biotechnology. These include the high regulatory system costs in developing and testing genetic engineered products, and additional costs which might be necessary to achieve consumer acceptance of food products from biotechnology. Biotech companies are on the front line fighting regulatory "battles" every day—hurdles which cost them a significant amount of time and effort in getting products or processes approved. Several university

researchers actively involved in biotech research also brought up these regulatory costs and associated delays to product development.

Many companies indicated that the high cost and delay involved with products of genetic engineering had caused them to shy away from recombinant DNA techniques and emphasize cell culture approaches in research and product development. Thus, the research allocation effects of these regulatory costs are a potential subject for in-depth analysis. Are genetic engineering projects at a significant disadvantage in competing for biotechnology research and development investment capital (and for university research funds)? While some regulators would disagree, some scientists suggest that the cost of generating data required for field testing approval for one product can cost \$250,000 or more, not counting the scientists' time. As a consequence, will genetic engineering projects offering only moderate improvements, and those which are not destined for large volume markets, be quickly dropped from the budget? Are there significantly fewer products with long research and development time requirements brought to commercial development because of these high regulatory costs? (This constraint on product development is possibly accentuated by the limited capital position of some small specialized biotech companies.) As genetically engineered consumer products enter the regulatory process, to what extent will the product

developers have to identify all the biochemical changes in the ultimate food product, a potentially extremely difficult and costly process?

Do the multiple U.S. federal regulatory agencies (USDA, EPA, FDA) and state agencies create significantly higher regulatory costs? They are developing and evolving a cooperative framework for biotechnology regulation, but there often can be overlapping jurisdictions that can lead to increased data and time required. Will the high regulatory costs in the United States prompt recombinant DNA research and development, field testing, etc. to move to countries with less stringent regulation? What is the implication for economic development of the U.S. biotechnology industry, in terms of the location of economic activity (jobs, tax base, etc.) in both research and manufacturing? Will the costs and the longer time lags to get regulatory approval put U.S. farmers, ranchers, and the food industry at a competitive disadvantage to other countries on the world market? Or will the research and the products of biotechnology move freely and easily across international borders, so U.S. food industry participants will not be at a disadvantage even if the primary biotech product developments occur elsewhere? Will less developed or third world countries be disadvantaged by biotechnologies requiring sophistication to use, or will they have advantages in developing or applying biotech innovations because of fewer regulatory constraints?

Consumer Acceptance

Consumer acceptance of the end products of biotechnology is a major concern of companies involved in research and product development. Consumer fears or adverse perceptions of biotech products, whether well-founded or unfounded, could stifle the adoption of some biotech products in agriculture or food processing. Thus, factors influencing consumer reactions could be an important focus of both publicly funded socioeconomic analysis and consumer market research in companies developing biotech products.

Biotech industry members expect that genetic engineering advances in food processing efficiency, disease prevention, biological alternatives to chemical sprays, etc. are more likely to go unnoticed and will not be a concern to consumers. However, their experiences with field testing some products and public reaction to some research announcements suggest that unanticipated consumer concerns and public responses can be very strong. In California, field testing bovine somatotropin in dairy herds prompted a reaction: Some processors refuse to use BST milk in their products, so as not to stimulate consumer fears about product safety and possibly boycott of their products. Despite no FDA restrictions on consumer use of BST milk, the concern is that hormones in milk, meat, or any other product may cause a negative consumer reaction, since typically consumers have little knowledge of the differences be-

tween various types of hormones. And some merchandisers might be tempted to capitalize on consumer fears through "negative advertising"; even if the fears weren't warranted, such actions could have a stifling effect on the use of new technology.

The ice-minus bacteria field tests by the University of California and by Advanced Genetic Systems prompted anxiety in neighbors and some test field destruction by activist groups. The lay public tends to equate any bacteria or virus with human disease, so it is not surprising that much education and public relations work may be needed when such organisms modified by genetic engineering are released in the environment. It is certainly easier to take a "not in my backyard" approach whenever there is any lingering perception of risk, even when it may not be well-founded.

New biotech products that involve toxins engineered into plants used for food production could spark some controversy, primarily from a safety perspective. And transgenic animals, especially novel ones, could prompt philosophical concerns among consumers, animal rights activists, and religious leaders or philosophers who might find either the product itself or the process of "tampering" with nature objectionable.

Some of these perceptions might be overcome with education, and anxieties calmed as products clear government regulatory hurdles. Some philosophical objections, however, are unlikely to be

resolved—although they may be counterbalanced by perceived benefits associated with new products.

These issues suggest a series of researchable questions about the economic impact of biotech innovations. The implications of consumer demand for biotech products are paramount to determining their probable economic impact in the food and agriculture sector and their potential economic benefit for the biotech product developer. Socioeconomic analysis should focus on the most likely consumer benefits and disadvantages of new products coming from biotechnology. Key performance measures probably would include consumer product price levels, quality, variety, availability, and possibly the impact on environmental quality. Will price levels rise or fall? Will product characteristics change enough to provide enhanced taste, texture, safety, shelf life? Will new flavors, colors, or entirely new products increase the variety of products available? Will the total or local supply of food products be increased, or their seasonal availability improve? Will there be less (or more) concern about the environment—air, groundwater, etc.—because of a particular biotech innovation in agriculture or food processing? Will there be fewer animal units or acres required, with corresponding changes in air and water pollution probabilities, and cultivation pressures on erosion-prone land? Such questions can begin to be addressed once the technical characteristics of a biotech

innovation become available from companies directly, through research articles in technical journals, from material presented to regulatory agencies before field-testing, and from patent applications.

After estimating the probable end-product effects (nutrition, taste, texture, etc.) and the associated microeconomic changes in consumer demand, agricultural production, food processing and distribution systems (probably working with technical specialists), social scientists can develop scenarios about the probable dynamic changes in the industry. From this, they can determine where research and information will be needed to predict aggregate consumer implications of a new biotech product.

A related consideration is consumer demand shifts that might occur in a market as products from biotechnology are introduced. Marketing firms will need to know these effects before determining whether they will handle a product; such shifts could affect the entire vertical marketing chain—food manufacturers, processors, farmers and ranchers. How much will end-product characteristics change? Will consumers notice or care? What labeling will be required? What claims (positive or negative) could be made by manufacturers, merchandisers of the product, as well as food editors or biotech critics? How will these affect consumer willingness to buy the product or to pay more for it (and how much more)? Technologies that are supply-increasing or those that improve food

processing efficiency could effect consumer prices. How would such supply shifts affect consumer price levels and how much would price changes affect consumption levels, consumer nutrition, and the market shares of competing commodities?

Thus, both demand and supply shifts and responsiveness are important to understand in determining where new equilibrium price-quantity relationships will lie and how much of a price change would be transmitted through the vertical marketing system to farmers and the biotech product developer. These factors can be critical determinants of whether farmers or food processors will adopt a new technology or whether the biotech company will be able to charge a price high enough to make a new product worth the investment.

A related question for biotech developers is the type and cost of consumer education required to facilitate acceptance of new products and to overcome fears that could adversely affect product demand. While many of these costs may decline as the public gradually becomes aware of biotechnology and has successful experiences with new products, early developers face the challenge of educating the public about the realities (and myths) associated with each new product. What media and what messages will be most effective? How much will the program cost, and who should bear the cost (biotech firms, food manufacturers, retailers, farmers, universities)?

Producer Acceptance

An important focus for socioeconomic analysis could be on producer acceptance and adoption of new biotechnology developments. This would include both their probable rate of adoption and factors influencing the rate, as well as more aggregate industry performance implications and the related distribution of benefits and costs. The microeconomic aspects, or individual farm or processing firm management decision framework, involved in the new technology adoption decision are basic behavioral issues for study. These are the building blocks necessary to determine the aggregate industry supply and demand dynamics as the new technology is absorbed into an industry and triggers shifts in demand, supply and competitive interrelationships.

Producer adoption rates would be expected to be related to the changes in the marketability of the end product; this involves the changes in the product characteristics and the perceived value and probable change in relative market price that would be paid by consumers. In addition, the production manager would consider the effects on yields and production efficiency, capital investments or management system changes required, and how they would fit into current operations. The corresponding overall evaluation of the perceived risks and expected profitability of adopting the biotech innovation would provide the key purchase or adoption criteria.

Related research issues would include determining the technical performance characteristics of the new product and economic tradeoffs in using it in individual farm or processing operations. Analysis of optimum adjustments for various types of firms, and surveys focused on producer willingness to adopt alternative technologies, could be useful in evaluating probable market penetration rates and key factors influencing receptiveness to the new technology.

Marketing analyses may also be important in determining whether changes in product characteristics affect perceptions of value at the consumer level (e.g., for a low-fat pork chop) or at the processor level (e.g., less low value fat to trim from pork loins). If there are changes in product characteristics, will corresponding changes in handling and distribution systems be required (and at what cost), will grading systems need to be changed, and will pricing systems have to adjust to reflect value differences at the retail or wholesale levels back to farmers using the new technology? How should the pricing systems and market institutions (e.g., government grading systems) change to accommodate biotech innovations?

The most important concern about biotechnology voiced by farmers (based on a small survey conducted at a California Farm Bureau conference on agricultural biotechnology) is its potential contribution to agricultural structure: to over production and lower farm prices, fewer

farmers and acres farmed, fewer farm workers, and related problems (see survey summary in the appendix). This is the type of concern that was raised about BST causing small dairy farmers to be forced out of business, motivating dairy farmers to picket and protest BST research at the University of Wisconsin.

It seems especially important for universities doing significant work in biotechnology to also do socioeconomic analyses of the probable industry supply and demand dynamics associated with products under development. Comprehensive analyses of the likely patterns of change in farm supply, consumer demand, and intermediate processing and distribution costs, can be extremely useful in making better informed public policy and private management decisions, and defusing inaccurate or biased perceptions.

Tracing through probable shifts in industry supply and demand allows projections of probable changes in consumer prices, consumption and nutritive value, farm production levels, commodity and land prices, and farm profitability, along with possible changes in demand for agricultural input suppliers. Farmers and food processors are typically concerned about whether their businesses will grow or decline in volume, and whether competition will be more or less severe. The implications of these projected patterns of change can then be examined for early adopters of the new technology; late (or non) adopters; producers of competing products; feed, seed,

and chemical suppliers; food processors and merchandisers. The question of possible changes in regional or international competitive advantage can be addressed, and the distribution of benefits to developed or less developed countries can be estimated. Implications for rural communities, government agricultural and trade policy can be examined. These analyses will help answer basic questions such as "Who are the beneficiaries?" and "Who are the losers?" Then, as biotechnology advances occur, an early warning system about probable stresses (or benefits) would be available for public policy response.

Agricultural Sector Structure

The changing structure of our food production, processing and distribution system is often the focus of socioeconomic analysis. The family farm and the associated way of life in rural communities have often been considered as adversely affected by technological change in agriculture in the post-World War II period. These structural issues are typically raised by farmers, rural residents, and politicians, but were not a major concern of the biotech companies surveyed.

The analysis of industry supply and demand dynamics can suggest which products competing for the consumer food dollar will gain a competitive advantage in quality or price from biotech innovations, and which ones would lose market share and volume. The relative growth or decline in market volumes

combined with projected changes in acreage, animal numbers and associated labor required, can be used to project probable changes in farm numbers and determine where there might be pressures to shift to other enterprises.

With some biotechnologies requiring capital investment or sophisticated management, the possible differences in adoption rates by farms varying in size or sophistication (probably positively correlated) can be studied to determine whether the technology is likely to be uniformly adopted. Will family farmers be adversely affected and, if so, are there steps (e.g., less capital- or management-intensive variations of these technologies) which could reduce those effects?

Adapting crops to better handle temperature stresses or local insect or disease problems, could significantly shift or expand areas of production. As producers change crop mix and geographic shifts in production patterns occur, processing locations could change as well. This would create shifts in job locations and economic activity in local communities. Regional shifts in competitive advantage associated with new technologies will be important to study.

A few biotech companies, especially those involved in developing value-added food products from plants, warned that the potential for increased vertical integration or contractual control of agricultural production may deserve analysis. Contract production or ownership of farms by processors may expand

to keep new products from getting into competitor's hands, especially when improved product attributes (e.g., different protein levels or fatty acid composition) are not readily obvious to graders or inspectors. Which types of biotech products are likely to lead to more vertical integration or contractual control of production? What are the primary implications for the structure of agricultural production?

Several biotech firms raised the matter of the future structure of the biotechnology industry, especially the likelihood of concentration of biotechnology research (from many relatively small operations) into the hands of a few major firms. Will greater concentration inevitably occur, and what will be the effects on biotech research and development expenditures, product introductions and competition? Similarly, they were concerned about the structural linkages that could form among specialized, often relatively small biotech research and development companies, and the seed, chemical and pharmaceutical companies who typically market the farm inputs to farmers and ranchers. Many entrepreneurs started biotech firms with the intention of eventually selling out to another firm, while others preferring independence might be more concerned about the trend toward concentration. Many small biotech "boutiques" are forced to do outside contract research for other companies to provide cash flow and maintain a critical scientific mass to develop their own products. A

few biotech firms are acquiring seed companies to merchandise a new germ plasma which they are developing, and thereby capture more of the benefits. Other biotech research firms have been acquired by companies as a convenient way of quickly entering or expanding their biotech research base and their future product introductions.

A related issue is the question of linked products (e.g., a herbicide-resistant variety of corn that can only be used with that broad spectrum herbicide) and their effect on competition in the farm input market. Similarly, mergers and acquisitions among biotech firms, or with other farm input suppliers, could affect the long-term rate of technological change, the type of farm inputs and the relative prices paid by farmers. Analysis of the probable evolution and implications of the competitive structure of firms would be useful.

University Biotechnology Research Issues

Most of the broad issues regarding the optimum mix of basic and applied research, the appropriate linkages between university research programs and the private sector have been discussed in some detail elsewhere (see National Association of State Universities and Land-Grant Colleges, 1986a and b). However, several points from the biotech industry survey have implications for the direction of university biotechnology research. Several biotechnology company

research managers noted that most basic knowledge which they employ in agricultural applications of biotechnology continues to come from universities.

Several specialized biotechnology companies acknowledged that their mix of biotech research and product development programs or projects was heavily influenced by the availability of capital (often very limited) and the need to generate operating money from product sales or licensing fees, or by doing contract research and product development for other companies. Entrepreneurial biotech firms were better able to attract outside investment capital ten years ago. However, the marketing of new biotech products has been slower than many investors hoped, and the sharp decline in capital value of stock in October 1987 has pressured biotech firms to generate operating capital from internal sources. Many smaller companies are putting their capital into the projects with the larger potential markets (at least \$10 million annual sales) and with shorter time periods until positive cash flows can be generated. Thus, basic research with its longer time horizon and uncertain commercial possibilities tends to be a relatively small part of private sector efforts whose primary endeavors will be new product development and commercial exploitation of these products. Since it seems reasonable for public sector research funds to be allocated into areas which augment or complement what the private sector will do, the current university emphasis on

basic biotechnology research seems quite appropriate and consistent with its comparative advantage.

However, the typical private sector investment requirement of a large potential market volume could keep many products for specialized, regional industries from being developed. New products for relatively smaller scale fruit and vegetable crops, for example, would only be pursued if they serve as prototypes for other larger volume crop applications, or if the same development could be readily adapted to several relatively small volume crops. Thus, it may make sense for some university biotechnology research funds to be allocated to product development for local or regional crops which don't meet private sector financial criteria. This might be especially important for states with highly diversified agriculture, like California, Florida, Michigan.

Private companies developing commercial biotech products typically are not concerned with the implications of their new products on the structure of farming. They do, however, tend to consider impacts in the other direction—how the size and number of farms will affect their sales projections. Also, some marketing managers may worry that small farmers would not buy a product when it is fit into a particular technology package. Meanwhile, farm interest groups, politicians, academics, and others are looking at the structural implications of new technologies. Public sector research funding might be justified in

transforming new biotech products, for example, one requiring significant sophistication or capital to use, into one more generally adaptable by all farm size classes. Such an effort could slow the movement of small and medium-sized producers out of agriculture.

The biotech firms surveyed also wondered how they could play a more effective role in addressing consumer fears and emotions about biotech products such as recombinant DNA or microbial changes in food and the environment. Private companies face these attitudes directly in the marketplace, but much public sector biotechnology funding could also be affected. Biotechnologists need to be aware of the lay public concerns and how best to respond. This broad educational need deserves more attention, and biotechnologists with the right combination of sensitivity and credibility have an important role to play. Biotechnology educators need to carefully point out all the risks and implications that can reasonably be expected, along with the scientific basis for and degree of confidence in that expectation, allaying any unfounded fears about biotech product safety. A better linkage of biotech experts with university researchers and extension specialists, undergraduate educators, and K-12 teachers may be essential to cope with increasing public questioning as these new products enter the market. Later, the general public's increased knowledge, experience with, and exposure to products from biotechnology may

ease these informational demands—especially if there are no adverse consequences from biotech development in the next five to ten years.

Many of these issues overlap—a fact often noted when requests for funding biotechnology research are before legislative committees or when agricultural or lay groups are being addressed on biotech. Academic administrators and biotechnologists are often asked how they can justify requests for increased agricultural biotechnology funding during a period of agricultural surpluses. Some logical answers to the issues raised need to be put before the public and explained in lay terms, including tangible illustrations, as new products enter the market. For example, the temporary versus permanent nature of surpluses, and their particular causes in some industries, could be brought out. Similarly, the contributions of new technologies to increased profits for early adopters (often temporary), and long-term improvements in consumer product availability, prices, or quality could be demonstrated. The analysis of the general benefits and costs of new biotech developments, and more specific analyses of individual new products entering the market should be a joint effort of biotechnologists and social scientists; findings will serve the public and the needs of research administrators in determining and justifying research priorities to funding agencies.

Cooperative Extension Issues

Among the issues raised by farmers and ranchers and by biotech company survey respondents, there are several that ought to be on the agenda of Cooperative Extension at land-grant universities. Both consumer concerns and the needs of the farmers and ranchers ought to be more effectively addressed by an organization which currently has very few individuals knowledgeable about biotechnology.

Farmers and ranchers will undoubtedly want extension specialists' objective analyses of the technical and microeconomic pros and cons of new products from biotechnology as they come to market. While the companies marketing the products will be providing detailed information about a new product and how to use it most effectively, unbiased analysis of technological alternatives will continue to be in demand by farmers and ranchers, especially by small and medium-sized firms. Extension specialists may be able to fill this need.

A new potentially more important educational role that extension can provide is an early warning system to farmers and ranchers regarding biotechnology advances in each major commodity production and processing system in their state and region. In what seems likely to be a more rapidly changing environment, early warning of imminent and important changes in technology can be very important in long-term strategic planning and investment decisions by individual farmers. Since the technical nature of potential

new technologies surfaces in journal articles, in applications for regulatory approvals or patents, and within the biotech industry itself a few years before a product is marketed, tentative evaluations of the likely performance effects can be made early on. The potential importance and influence on farmers' operating practices, yields, costs, and end product characteristics and value can be analyzed. A team effort involving biotechnologists, production specialists, and agricultural economists could determine the technical effects of a product, the farm management adjustments required, the potential benefits and costs to the individual farmers, the associated marketing system adjustments, and the aggregate industry implications.

In addition, marketing extension specialists could assist farmers and farm organizations, processors and merchandisers in getting value-added improvements in farm and related consumer products identified in the grading system and reflected in the prices paid at each level of the marketing system.

While allaying consumer fears or enhancing consumer appreciation of agricultural product improvements will be important, extension specialists can also play a useful role in the education process at the farm level. Education of consumers and farmers will be an important role for extension specialists in the next five to ten years as many new biotech products enter the market. Neither farmers nor consumers have much knowledge

about biotechnology, but often have perceptions or fears. Their educational needs could be beyond the current capacity and ability of many extension services unless significant investment in training is made, knowledgeable personnel are employed, and the link with biotech researchers is strengthened.

Summary and Conclusions

Before their commercial market introduction, some agricultural biotechnology products developed using genetic engineering have stirred up significant public controversy. A survey was conducted of 24 leading agricultural biotechnology research and development firms. This was supplemented with reviews of current biotechnology literature and interviews with university biotechnologists. The primary purpose was to determine the probable types and timing of new biotechnology products becoming commercially available in plant and animal production and food processing during the next decade, and the related issues and implications which might deserve socioeconomic analysis. In addition, possible implications for university agricultural research and extension programs were briefly considered.

While a relatively small number of biotechnology products are now in use, there are more that will gradually reach the marketplace in the next few years, with new products coming at an increasing rate during the remainder of the decade. Initially, only a small proportion

of the new products will be based on genetic engineering, due to the greater costs and regulatory system time delays for this type of product. Currently, many biotech companies are more aggressively pursuing projects that require more conventional biotechnology techniques, because of the costs and time delays associated with genetic engineering.

In the next five years, the most noteworthy new products are likely to be growth stimulants (porcine and bovine somatotropins) enhancing milk and lean pork production, a number of biopesticides for insect or plant disease control in some major crops, and the first commercial agricultural crops from genetic engineering (e.g., herbicide-resistant, insect-resistant, virus-resistant tomatoes).

Value-added plant characteristics will be forthcoming from tissue culture methods, including higher solids content in some processing crops, natural flavors produced by cell cultures, textural or taste changes in fresh vegetables and popcorn, and new colors in ornamental crops, but the progress may be slow. While advances will be made in enzyme technology and fermentation processes and products at the food processing level, these improvements will not be as obvious at the consumer level.

In five to ten years from now, there will be an expansion in new product development and a more rapid rate of market entry, especially by products derived from genetic engineering. Multiple gene transfer products in the more

scientifically difficult but larger commercial crops like major grains and oil seeds, could lead to improved yields, better standability, more stress resistance, as well as tolerance to herbicides, insects, nematodes, or other pests. Value-added consumer characteristics, including improved composition of starches, fatty acids, or proteins will be likely in some important crops near the end of the decade. The livestock and poultry sector will be using a number of second-generation growth stimulants, and, possibly, the first transgenic animal with enhanced growth hormone production or disease resistance will be introduced.

The products emerging from biotechnology will prompt an increasing number of questions and issues by the public, by farmers and ranchers, and by public policy makers. Land-grant universities need to consider how to effectively provide the research and education programs that will contribute to better public and private sector decisions.

While philosophical issues can and should be discussed, other questions are better candidates for analysis. For example, public perceptions about the risks associated with biotechnology public policy and the regulatory process. Universities can provide research in biotechnology and its socioeconomic implications to facilitate better-informed public and private decisions. Some new products may mean quantum leaps in technology, with significant influence on which industries grow and prosper. Consumers'

reception of products coming from biotechnology can be critical in their success or failure. So, the benefits and disadvantages to consumers deserve analysis, along with the factors influencing consumer perceptions. Longer-term demand and supply shifts caused by biotech products need analysis to predict who will gain and who lose from anticipated technological changes. Probable structural changes in farming, biotech and farm input industries could also be important to study.

Land-grant universities should consider which of the following adjustments in program direction and organization might fit their situation in the dynamic and challenging environment of the next decade:

- (1) Increasing biotechnology safety research and assessment.
- (2) Allocating some biotech research funding to small, regional industry product development work.
- (3) Enhancing small farm adaptability of biotech advances.
- (4) Analyzing the socioeconomic implications of biotech products before they reach the market.
- (5) Expanding public and consumer adult education and extension programs on biotechnology product safety, advantages, and disadvantages.
- (6) Providing farmers and ranchers with early warning analyses of expected biotech products that might

- influence their strategic planning and investment decisions.
- (7) Integrating biotech research, socio-economic research, and extension programs to provide useful interdisciplinary analyses and educational programs.

The issues raised and questions posed about biotechnology are important

and need to be addressed long before commercial market introduction of certain products. This suggests that universities need to anticipate the technological changes that are coming, and consider making strategic staff and organizational changes now so that they can be prepared to make an effective response to the public during the next decade.

Appendix. California Farm Bureau Biotechnology Conference
Farmer and Agribusiness Survey Results

Primary Agricultural Biotechnology Problems or Issues

Number out of 29 respondents who mentioned the problems

- 12 Potential contribution to over production of agricultural commodities, with corresponding effects of lower farm commodity prices, less agricultural acreage, reduced number of farmers and farmworkers, etc.
- 7 Consumer or public acceptance of biotechnology and products derived from biotechnology.
- 7 Need to educate the public and farmers regarding the benefits and costs of biotechnology.
- 7 Resistance to manipulating nature, with related risk of deadly mutations or undesirable side effects.
- 6 Public misconceptions of biotechnology, often prompted by radical elements impeding scientific progress by preying on public fears.
- 5 Regulatory problems and regulations of biotechnology.

Most Important Benefits or Opportunities

Number out of 29 respondents who mentioned the benefits

- 19 Improved plant and animal strains, including one or more of the following: improved yields, growth, disease resistance, pest resistance, herbicide resistance, nitrogen fixing, etc.
- 15 Reduced use of chemicals, drugs, or toxic substances in agricultural production by genetic selection or manipulation, or biological controls.
- 14 Improved food, fiber, and forest product quality and availability for consumers.
- 8 Lower cost and improved profits for farmers, index cost to consumers.
- 4 New alternative crops.

Their Level of Understanding of Biotechnology

Very Good	Good	Fair	Poor	Very Little	<u>Total</u>
3	11	14	1	0	29

Their Perception about Benefits Exceeding Costs of Biotechnology*

	Definitely <u>Yes</u>	Probably <u>Yes</u>	About <u>Equal</u>	Probably <u>Not</u>	Definitely <u>Not</u>	<u>Total</u>
For You	4	18	6	2	0	30
For Farmers	5	19	4	3	0	31
For Society	15	13	0	2	1	31

*Two respondents filled in last question only, but listed no problems or benefits; one didn't list a perception "For You."

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